

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

Y-TRAP, INC.,

Plaintiff,

v.

BIOCON LTD. AND BICARA  
THERAPEUTICS, INC.,

Defendants.

C.A. No. 1-24-cv-12678-GAO

**ORAL ARGUMENT REQUESTED**

**PENDING MOTION FOR LEAVE TO  
FILE EXCESS PAGES (Dkt. No. 51)  
FILED ON JANUARY 17, 2025**

**MEMORANDUM OF LAW IN SUPPORT OF  
DEFENDANT BIOCON LTD.'S MOTION TO DISMISS THE COMPLAINT**

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## INTRODUCTION

Y-Trap’s principal claim for correction of inventorship—asserting that Y-Trap’s founders (Drs. Bedi and Ravi) solely invented the Biocon patents—fails on numerous, independent grounds. Y-Trap fails to plead it has standing to bring its inventorship claim in the first place. Even if it did, Y-Trap fails to plausibly allege any facts supporting this claim. And what little factual content the Complaint does contain shows undoubtedly that Y-Trap’s attempt to assert inventorship comes too late; even on this motion to dismiss, the claims are barred by laches.

As to standing, the Complaint fails to allege that Y-Trap has any interest in the outcome. It appears to allege that if Bedi and Ravi are added as inventors, the result would be that Johns Hopkins University (“JHU”)—which employed them at the relevant time—would own (or perhaps co-own together with Biocon) the Biocon patents. But where is JHU, and what is that to Y-Trap? Y-Trap alleges that it has a license from JHU for the so-called Bedi ’789 IP, which it says is similar to the Biocon patents, but does not allege that JHU also granted Y-Trap a license to the Biocon patents themselves. It would be remarkable if JHU had done so, given that JHU (i) filed a proceeding at the USPTO alleging that the first in the series of Biocon patents was invalid, and (ii) represented to the USPTO as a requirement for that filing that it did not own that Biocon patent.

On the merits of the claim itself, Y-Trap fails to plausibly allege that its principals (Drs. Bedi and Ravi) are either (i) joint inventors (together with the Biocon inventors) of the Biocon patents, or (ii) sole inventors of the patents. Y-Trap seems to allege only the latter, which would require it to plead that none of the named Biocon inventors qualify as inventors of even one claim of any patent. The Complaint nowhere tries to make out that assertion. But even if Y-Trap contends that its principals are joint inventors, the well-pled facts in the Complaint are insufficient.

Of the nine Biocon patents named in the Complaint, Y-Trap only attempts to allege similarity between prior work of Drs. Bedi and Ravi and, which is U.S. Patent 8,815,247 (“the

'247 patent"). The '247 patent discloses certain specific kinds of "fusion proteins" (here, proteins that combine three pieces; (1) a targeting antibody made up of a "light" amino acid chain, a "heavy" amino acid chain or both; (2) connected with an amino acid "linker" in the middle to; (3) an immunomodulating moiety that targets certain proteins in the body. Y-Trap alleges the heavy chain of the '247 patent is similar to Dr. Bedi's prior work, but the Complaint's allegations confirm that (1) the heavy amino acid chain is not the same as Dr. Bedi's prior disclosures; (2) the amino acid "linker" in the '247 patent is different than any prior disclosure; and (3) no prior Bedi/Ravi disclosure contained the specific combination of all the specific pieces claimed in the '247 patent. On its face, the inventorship claim fails. The remaining eight patents are easily disposed of as well: two concern amino acid chains and protein targets unrelated to any invention by Drs. Bedi and Ravi. The six remaining patents claim methods of using certain fusion proteins, but the Complaint nowhere alleges that Bedi and Ravi conceived of any such methods.

Still further, the inventorship claim should be dismissed for laches. The problem is most acute with the '247 patent, which is the only patent on which the Complaint focuses. A presumption of laches arises after six years. The '247 patent issued ten years ago. Y-Trap fails to plead why the presumption would not apply. In fact, the pleadings alone show Y-Trap was actually aware of the '247 patent for over than six years. The Complaint itself pleads facts showing both (i) unreasonable delay, and (ii) prejudice to Biocon from that delay.

Finally, Biocon is entitled to dismissal of Y-Trap's state-law claims (i) for lack of personal jurisdiction, (ii) under the statutes of limitations, (iii) for failure to plausibly plead the required elements of those claims, and (iv) because they are preempted by the Patent Act.

#### **A. The Parties**

Biocon is an Indian pharmaceutical company that owns U.S. patents (the "Biocon Patents") that are subject to Y-Trap's claim for correction of inventorship under 35 U.S.C. § 256, including

the first in this series, which is the '247 patent. Compl. ¶¶ 5, 6 n.2, 108. Defendant Bicara is the licensee of the '247 patent and other patents, and has been pursuing research and development of a drug for cancer known as ficerafusp alfa (or BCA101). *Id.* ¶¶ 65-67. It is a fusion protein.

Y-Trap claims to be a start-up company founded in September 2015 by Dr. Atul Bedi and Dr. Rajani Ravi, *id.* ¶48, who previously founded a company called IATRICa in collaboration with Biocon, *id.* ¶ 27. In 2012, Biocon (in its capacity as an IATRICa shareholder), complained that Bedi improperly assigned to JHU, his other employer, patent applications that rightfully belonged to IATRICa. *Id.* ¶¶ 27, 45; Ex. 20 (Del. Compl.) and Ex. 21 (Del. Compl. Ex. C – Demand Letter).<sup>1</sup> Y-Trap refers to them as the '789 Bedi IP based on the first publication in that family, WO 2011/109789, which published in September 2011. *See* Compl. ¶ 2 & n.1; Ex. 22 at 1.

#### **B. The Inventions Claimed in Biocon's '247 Patent and Patent Family**

The Complaint identifies only one Biocon patent alleged to have copied the '789 Bedi IP—the '247 Patent. *See* Compl. ¶ 41. The '247 patent claims as its invention a chimeric fusion protein that requires specific parts (“moieties”), with specific sequences, that are linked in a specific way, at a specific amino acid, by a specific amino acid spacer of a specific length that permits each moiety to bind to its respective target. Ex. 1 ('247 patent), Claim 1.

#### **C. The Alleged '789 Bedi Invention and Dr. Bedi's Alleged Disclosure to Biocon**

Y-Trap says that Bedi and Ravi conceived of inventions described in two provisional patent applications filed in 2010 and 2011 and assigned to JHU. These applications were the start of the '789 Bedi IP. Y-Trap also says that Bedi disclosed some amino acid sequences in the 2010 application, reproduced in Exhibit A to the Complaint, to Biocon around that time. Compl. ¶¶ 41-

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<sup>1</sup> Exhibit numbers refer to exhibits attached to the Declaration of Charles A. Weiss, filed concurrently herewith.

42 and Ex. A at 3; *see also* ¶¶ 29-30, 37, 53. Y-Trap does not allege that these applications belonged to Bedi himself, or explain why he disclosed them to Biocon if they belonged to JHU.

Nor does the Complaint allege that Bedi conceived the claimed invention of Biocon’s ’247 patent, which is not just a sequence, but rather an entire chimeric fusion protein with specifically required parts assembled in a particular arrangement with specified characteristics. The Complaint says only that Bedi conceived of and disclosed pieces of a protein that have similar sequences to some parts of the complete fusion protein claimed in the ’247 patent. *See id.* ¶¶ 41-42 and Ex. A at 3. Y-Trap ignores that necessary portions are missing, but admits the differences between the allegedly-disclosed sequences and the purported corresponding parts of the fusion protein claimed in the ’247 patent, including that (i) the heavy chain is not the same, and (ii) the linker is not the same. *See, e.g., id.* ¶ 42 and Ex. A at 3.

Despite these omissions and differences, Y-Trap asserts in conclusory fashion that the Biocon Patents are “copy cats” of the ’789 Bedi IP. *Id.* ¶¶ 6, 39-40. The same argument (that the admitted differences in the sequences were insignificant and obvious, and that specific combination of the whole invention would be apparent from the piecemeal difference sequences) was made ten years ago by JHU, owner of the ’789 Bedi IP, in an attempt to invalidate the Biocon ’247 patent. *Johns Hopkins Univ. v. Biocon Ltd.*, Case IPR2016-00175, Paper 2 (Petition) (Nov. 10, 2015), Ex. 23. The Patent Trial and Appeal Board (“PTAB”) rejected the arguments then, and they are implausible now. *See id.*, Paper 9 (Decision Denying IPR) (May 12, 2016), Ex. 24.

## **ARGUMENT**

### **I. Y-TRAP LACKS STANDING FOR ITS SECTION 256 INVENTORSHIP CLAIM**

Invocation of § 256 in court requires constitutional standing. *See Chou v. Univ. of Chicago*, 254 F.3d 1347, 1357 (Fed. Cir. 2001). Y-Trap must establish three elements to meet the “irreducible constitutional minimum of standing:”

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

*Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).<sup>2</sup> Y-Trap fails to plead facts showing (i) injury in fact suffered personally by it (ii) that is fairly traceable to Biocon’s conduct.<sup>3</sup>

#### **A. Y-Trap Has No Legal Interest In The Outcome Of Its Inventorship Claims**

Y-Trap does not assert that it would own the Biocon Patents if its inventorship claims succeed. It hints at some interest via JHU, but the Complaint does not allege that JHU licensed rights in the Biocon Patents to Y-Trap, and it is implausible that JHU would have licensed patents it does not own. The allegation that Y-Trap has a license from JHU to the Bedi ’789 IP, which is assigned to JHU, Compl. ¶ 2, says nothing about JHU having granted Y-Trap purported rights to the Biocon Patents. And JHU is conspicuously absent from this case.

Worse, JHU certified that it did not own Biocon’s ’247 patent when it petitioned for an IPR.<sup>4</sup> JHU could not have otherwise filed its IPR petition, because the one person or entity that is categorically denied the right to file an IPR petition is the patent’s owner. 35 U.S.C. § 311(a).

#### **B. Y-Trap Does Not Allege A Concrete Non-Abstract Monetary Or Reputational Injury And Fails To Establish The Second Element Of Standing Because The**

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<sup>2</sup> Except where noted, internal quotations and citations are omitted, and emphasis is added.

<sup>3</sup> Y-Trap also fails to allege facts that demonstrate the third prong. For brevity Biocon does not fully address that failure in this brief, but, in short, Y-Trap fails to plausibly allege redressability for similar reasons it fails on the second prong: the connection to Y-Trap’s alleged injury is speculative.

<sup>4</sup> See Ex. 23 (IPR Pet.) at cover page (naming Biocon as patent owner); 2 (“Proof of Service on Patent Owner” and “Grounds for Standing”). The JHU Petition did not have page numbers in the body, but page 2 refers to the second page in the body, following the Table of Exhibits.

**Connection Between The Injury Alleged And The Conduct Complained Of Is Not Fairly Traceable To The Actions Of Biocon**

Y-Trap does not plead a concrete and particularized injury that is traceable to inventorship of the Biocon Patents. It states that Biocon’s alleged actions “hindered Y-Trap’s ability to secure crucial funding, form joint ventures, establish partnerships in the biotechnology sector and, ultimately, develop multiple life-saving immunotherapies for cancer,” Compl. ¶¶ 13, 90-95, but not that it would have accomplished anything if JHU owned the ’247 patent.

Y-Trap’s constitutionally deficient allegations of harm are similar to those alleged in *Kamdem-Ouaffo v. PepsiCo Inc.*, 657 F. App’x 949, 954 (Fed. Cir. 2016) (nonprecedential), in which the Federal Circuit affirmed the district court’s dismissal of a § 256 claim for lack of standing. In that case, the allegation was that the plaintiff “sustains and/or might sustain damages in terms of the loss of the ownership, inventorship, recognition, and the honor for his . . . Intellectual Property.” *Id.* The Federal Circuit found this to be an insufficient “bare assertion,” and explained that “[a]n allegation that one ‘sustains and/or might sustain’ injury, including reputational injury, is not ‘concrete and particularized,’ but rather ‘conjectural or hypothetical.’”

**II. Y-TRAP FAILS TO STATE A PLAUSIBLE CLAIM FOR CORRECTION OF INVENTORSHIP UNDER 35 U.S.C. § 256**

To survive a motion to dismiss, the Complaint must state sufficient “‘non-conclusory’ and ‘non-speculative’” facts, *Barchock v. CVS Health Corp.*, 886 F.3d 43, 48 (1st Cir. 2018), that would allow the Court to draw a “reasonable inference that the defendant is liable for the misconduct alleged,” *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 12 (1st Cir. 2011); *see also Penalbert-Rosa v. Fortuno-Burset*, 631 F.3d 592, 595 (1st Cir. 2011) (“The plaintiff’s factual allegations are ordinarily assumed to be true . . . . But ‘ordinarily’ does not mean ‘always’: some allegations, while not stating ultimate legal conclusions, are nevertheless so threadbare or speculative that they fail to cross ‘the line between the conclusory and the factual.’”).

In making this assessment, the Court may consider the “complaint’s well-pled (*i.e.*, non-conclusory, non-speculative) facts,” documents included or incorporated into the complaint, and matters of public record. *Schatz v. Republican State Leadership Comm.*, 669 F.3d 50, 55–56 (1st Cir. 2012); *see also Cruz-Arce v. Mgmt. Admin. Servs. Corp.*, 19 F.4th 538, 543 (1st Cir. 2021).

Inventorship of an issued U.S. patent is presumed to be correct, and the burden to change it is by clear and convincing evidence. *Univ. of Pittsburgh of Commonwealth Sys. of Higher Educ. v. Hedrick*, 573 F.3d 1290, 1297 (Fed. Cir. 2009); *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004). At the pleading stage, the complaint must set forth sufficient facts to plausibly make the case of inventorship. *CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1358-59 (Fed. Cir. 2019).

Inventorship requires conception, *id.* at 1358, which in turn “must include every feature of the subject matter claimed.” *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). A party seeking to remove all the named inventors (misjoinder) must show that they “did not contribute to the invention of any of the allowed claims.” *Hedrick*, 573 F.3d at 1297.

For purposes of this motion, the Biocon Patents can be divided into three categories: (i) the ’247 patent—the only patent that the Complaint addresses with any specifics—is addressed in section A below; (ii) two patents directed to proteins that the Complaint does not connect to the purported ’789 Bedi IP are addressed in subsection B(1) below; and (iii) six patents directed to methods, similarly unlinked to anything in the Complaint, are addressed in subsection B(2) below.

**A. Y-Trap’s Non-Conclusory, Non-Speculative Allegations Fail To State A Plausible Claim For Correction Of Inventorship Of The ’247 Patent**

**1. The Complaint Does Not Allege Conception Of The Entire Invention**

To state a claim for correction of inventorship, the Complaint must plead sufficient facts to plausibly infer conception of the entire invention claimed in the patent. *See Ethicon*, 135 F.3d

at 1460; *James v. J2 Cloud Servs., LLC*, 823 F. App'x 945, 949-50 (Fed. Cir. 2020) (affirming party claiming sole inventorship of a patent must show they “conceived and possessed every feature recited in the claims”). The Complaint does not even allege that.

The claim of the '247 patent can be thought of as an assembled puzzle with pieces that can be combined in different arrangements: when starting with just the pieces, the puzzle has multiple solutions. To state a claim for inventorship, the Complaint needs to plausibly allege, at minimum, that (i) Bedi and Ravi conceived of all the pieces; (ii) conceived a specific way of assembling them; (iii) conceived of this assembly working as described in the claim; and (iv) no one at Biocon conceived of any of this. Starting with the '247 patent, the pieces of the puzzle are a targeting moiety; a linker; and an immunomodulating moiety. But not just any moiety, just the specific ones claimed in the '247 patent. The targeting moiety is SEQ 5 or SEQ 6. The linker is SEQ 3 or SEQ 11. The immunomodulating moiety is SEQ 4. And they have to be put together in a certain way: (SEQ 5 or SEQ 6) attached at the C-terminus to (SEQ 3 or SEQ 11) attached to SEQ 4. The Complaint does not allege that Bedi and Ravi conceived of the pieces or how to put them together. To the contrary, it acknowledges (as the PTAB found) that SEQ 5 (the heavy chain) is different than the sequence Bedi/Ravi allegedly invented. Nor does the Complaint allege that that Bedi/Ravi came up with SEQ 11. And there are issues around SEQ 3, too (which in the claim is a threepeat, *i.e.*, repeated three times in sequence). And there is no allegation that they put it together as SEQ 6 (the light chain) C-terminus to (SEQ 3) (the linker, with three repeating units) to SEQ 4 (the immunomodulating sequence). Without alleging these facts, the Complaint does not state a claim for misjoinder or nonjoinder.

First, the Complaint does not allege that Bedi conceived of the linkers of the fusion protein claimed in the '247 patent. The light chain Dr. Bedi allegedly disclosed includes a linker that is



GGGGS, which can also be written as (GGGGS)<sub>1</sub> (the subscript “1” indicating that the group is not repeated). Compl. Ex. A at 3. But the claim of the ’247 patent requires different linkers, which must be of sufficient length to ensure that each moiety can bind to its respective target, and specifies such linker is either GGGGSGGGGSGGGGS, which can also be written as “(GGGGS)<sub>3</sub>” (Biocon Seq. ID No. 3) or EPKSCDK (Biocon Seq. ID No. 11).<sup>5</sup> The Complaint does not allege that Dr. Bedi disclosed or conceived of EPKSCDK (Biocon Seq. ID No. 11) or the threepeat linker, and the linker it says he did disclose differs from both Biocon linkers.

The Complaint also alleges that Dr. Bedi disclosed a heavy chain that is similar to but not the same as the heavy chain of the ’247 patent. *See* Compl. ¶ 42 and Ex. A. The claim of the ’247 patent requires a heavy chain (Biocon Seq. ID No. 5) that ends with a glycine (G or Gly). Compl. Ex. A at 3.<sup>6</sup> The heavy chain that Dr. Bedi allegedly disclosed (“2010 JHU Provisional – SEQ ID NO. 4”) ends with a lysine (K) and not a glycine (G). Compl. ¶ 42 and Ex. A. The Biocon invention claimed further specifies that when attaching to the heavy chain the amino acid spacer must attach to a glycine.<sup>7</sup> This is not the same as attaching to a lysine. In the heavy chain sequence disclosed by Dr. Bedi, it would not be possible for the immunomodulating moiety to attach via a linker (or “amino acid spacer” as referred to in the language) to a glycine because there is no

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<sup>5</sup> *See* Ex. 1 (’247 patent), cl. 1 (“wherein the targeting moiety and the immunomodulating moiety are linked by an amino acid spacer of sufficient length of amino acid residues so that both moieties can successfully bind to their individual target”); *id.* (“wherein the amino acid spacer is selected from SEQ ID NO: 3 or SEQ ID NO: 11”); *id.* Col. 29 (showing Seq. ID No. 3); *id.* Col. 39 (showing Seq. ID No. 11). The Seq. ID No. 11 letters EPKSCDK are abbreviations for the following amino acids: E or Glu = glutamic acid; P or Pro = Proline; K or Lys = Lysine; S or Ser = Serine; C or Cys = Cysteine; D or Asp = Aspartic Acid.

<sup>6</sup> *See also* Ex. 1 (’247 patent), cl. 1; *id.* Col. 6:8-16, Col. 29:32 (showing Seq. ID No. 5 ending with Gly) & Fig. 2 (illustrating an example showing Seq. ID no. 5.).

<sup>7</sup> *See* Ex. 1 (’247 patent), cl. 1 (“wherein SEQ ID NO: 4 [(the immunomodulating moiety)] is attached via the amino acid spacer to the C-terminus of SEQ ID NO 5 [(the heavy chain ending with glycine at the C-terminus)] or SEQ ID NO: 6 [(the light chain)].”).

glycine. The Complaint pleads no facts to support the conclusory allegation that these differences are “insignificant” in the context of biotechnology patent claim of the ’247 patent that is expressly limited to specific sequences arranged in a specific manner.

Finally, the Complaint does not allege that Bedi conceived of or disclosed either (1) all of the specific pieces claimed in the protein in the ’247 patent, or (2) the combination of those specific pieces. The Complaint fails to plausibly allege that Dr. Bedi disclosed to Biocon combining the allegedly disclosed heavy chain with the allegedly disclosed light chain fusion protein. This is another example of how the Complaint does not allege conception of the whole invention, *i.e.*, it does not allege that disclosure combined the sequences claimed in the ’247 patent.

## **2. Y-Trap Repeats JHU’s IPR Arguments That Fail To Plausibly Allege Conception Of The Entire Invention Claimed In The ’247 Patent**

JHU already challenged Biocon’s invention, and specifically challenged the heavy chain ending with a glycine amino acid at its C-terminus as being the same as the heavy chain ending with a lysine amino acid at its C-terminus. *See* Ex. 23 (IPR Pet.); Ex. 24 (IPR Decision) at 2-3.<sup>8</sup> JHU also previously made the argument that by disclosing similar sequences, the Biocon invention was disclosed in its entirety. *See* Ex. 23 (IPR Pet.) at 3, 5-6, 8-10. These arguments were already rejected by the PTAB. *See* Ex. 24 (IPR Decision) at 2-3.

In 2015, JHU asked the PTAB to institute an IPR to invalidate the ’247 patent on the grounds that it is was anticipated or rendered obvious based on U.S. Patent No. 8,993,524 (the

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<sup>8</sup> The IPR proceedings are facts of public record that are not subject to reasonable dispute that the Court may consider in weighing the overall allegations on a 12(b)(6) motion without converting it into a motion for summary judgment. *See Cruz-Arce v. Mgmt. Admin. Servs. Corp.*, 19 F.4th 538, 543 (1st Cir. 2021); *CODA*, 916 F.3d at 1360; *Boateng v. InterAmerican Univ., Inc.*, 210 F.3d 56, 60 (1st Cir. 2000) (“[A] court may look to matters of public record in deciding a Rule 12(b)(6) motion without converting the motion into one for summary judgment.”). The IPR proceedings on the ’247 patent and decision denying institution is of public record, see USPTO, IPR Decisions, Proceeding #IPR2016-00175, publicly available at <https://developer.uspto.gov/ptab-web/#/search/documents?proceedingNumber=IPR2016-00175>.

“Bedi ’524 patent”), which was the first patent to issue from the ’789 Bedi IP. *See* Ex. 23 (IPR Pet.) and Ex. 24 (IPR Decision) at 4-5, 8. JHU argued that Figure 3 of the Bedi ’524 patent depicted a fusion protein that anticipated claim 1 of the ’247 patent, however the PTAB found that JHU failed to show that Figure 3 anticipated claim 1 because there were differences between Figure 3 and claim 1. There were other differences noted by the PTAB, but of particular relevance here, was the requirement for a specific heavy chain sequence that ends with a glycine (G) amino acid and not a lysine (K) amino acid, such that a linker could attach at the glycine amino acid:

The central dispute in this case surrounds a further limitation in claim 1, which requires that the immunomodulating moiety (identified as SEQ ID NO: 4) “is attached via the amino acid spacer” (selected from SEQ ID NO: 3 and SEQ ID NO: 11) “to the C-terminus of SEQ ID NO 5 or SEQ ID NO: 6.” [’247 patent] at 70:42-44 (claim 1) (emphasis added). Critical to our analysis, the ’247 patent specification discloses that the amino acid residue at the C-terminus of SEQ ID NO: 5 is glycine (“Gly” or “G”), while the C-terminus of the anti-EGFR1 heavy chain in the prior art has an extra amino acid, lysine (“Lys” or “K”), to which the spacer is fused. *Id.* at col. 31.

\* \* \*

Petitioner [JHU] contends that Figure 3 depicts “[t]he identical fusion construct” of claim 1, but does not explain adequately how or why an ordinary artisan, reading Bedi, would have understood that the spacer attaches to a heavy chain sequence at the amino acid specified in claim 1.

\* \* \*

The Petition refers to the amino acid spacer as a “linker” or “linker sequence.” Pet. 4, 12. The Petition acknowledges that the “heavy chain sequence in Bedi” differs from claim 1 “in the addition of a C-terminal lysine (K) prior to the linker sequence.” *Id.* at 17. Both parties agree that Bedi’s amino acid spacer sequence is attached to a carboxyl group on a lysine residue at the terminus of the heavy chain; whereas in claim 1, the amino acid spacer sequence is attached to a carboxyl group on a glycine residue, when the heavy chain (SEQ ID NO. 5) is selected for the fusion protein. *Id.* at 17; Prelim. Resp. 16-17.

The Petition fails to explain how, in spite of that difference, the “heavy chain” fusion protein depicted in Bedi’s Figure 3 anticipates claim 1. Pet. 17, 19. On that point, the Petition states that Bedi’s Figure 3 depicts a “construct comprising” the requisite components of the invention, but does not explain why Bedi’s disclosure of a lysine residue, on the C-terminus of the heavy chain sequence, teaches the specific fusion protein recited in claim 1. (citations omitted).

Ex. 24 (IPR Decision) at 3, 6.

Given that anticipation essentially requires complete identity, the PTAB analyzed the same claim alleged, and found that there was no reasonable basis to infer the '247 patent was the same as the Bedi invention. *See id.* at 3, 5-6.

Indeed, the PTAB found that JHU had not even shown that the claim of the '247 patent was obvious (a lesser standard) over the Bedi disclosure. *See id.* at 8-10. JHU had argued that a person of ordinary skill in the art would have understood disclosure of a heavy chain ending with lysine (K) to be the same as a heavy chain with a glycine (G) amino acid. *See id.* at 3, 5-7, 8-10. Y-Trap reprises that failed argument here, *e.g.*, that disclosure of similar sequences is good enough.

### **3. Y-Trap Fails To Plausibly Allege That The Named Inventors Did Not Contribute To Conception, Which Is Fatal To A Claim For Misjoinder**

Similarly, the Complaint only asserts the conclusory allegation that the named Biocon inventors did not contribute to conception of the invention, based on the argument that a “single amino acid deletion was, in any case, already well-known in the art for any antibody, and as such, does not constitute an inventive contribution by Biocon scientists.” Compl. ¶ 42. As discussed above, this conclusion is not plausible, and the argument that the difference between the heavy chain ending in glycine versus lysine simply being obvious was already rejected by the PTAB.

The Complaint also misses the mark as to the entire invention conceived. *See Ethicon*, 135 F.3d at 1460. In addition to the differences, the '247 patent claim is for a particular combination of the sequences, and there is no allegation that Drs. Bedi or Ravi conceived of this combination. Again, the PTAB found that the Bedi reference did not disclose the combination. *See Ex. 24 (IPR Decision)* at 3, 6, 9. Y-Trap, similarly here, has not and cannot allege that the particular combination claimed was not inventive with respect to conception by the named inventors.

Even at the pleading stage, the Complaint must include more than conclusory statements in order to plausibly rebut the presumption that the named inventors are correct. *See Ashcroft v.*

*Iqbal*, 556 U.S. 662, 678 (2009); *Hedrick*, 573 F.3d at 1297. Because Y-Trap has not plausibly alleged that the named inventors did not conceive of any part of the claims (misjoinder), the Complaint fails to state a claim for substitution of inventors (sole inventorship by Bedi and Ravi).

**4. JHU’s Ownership Of The ’789 Bedi IP, Absence Of Inventorship Claims By JHU, JHU’s Assertion Of Standing As A Non-Owner To Bring An IPR, And The Patent File Histories Make Y-Trap’s Claims Implausible**

JHU’s filing of an IPR against the ’247 patent further renders Y-Trap’s inventorship claim implausible. First, this is because the one party that is categorically excluded from filing an IPR against a patent is the patent owner. 35 U.S.C. § 311(a). JHU’s assertion that it was not the owner of the ’247 patent when it filed the IPR and certified that it had standing to bring the IPR<sup>9</sup> contradicts Y-Trap’s allegations that JHU is the lawful owner of Biocon’s ’247 patent. Second, the Complaint does not provide any plausible reasons as to why JHU would seek to invalidate the ’247 patent by alleging that Bedi was prior art if, as now alleged by Y-Trap, Bedi was the inventor of the claimed subject matter and JHU was its owner via assignment from Bedi.

**B. Y-Trap Fails To State A § 256 Claim As To The Other Biocon Patents**

The Complaint fails to state a claim for correction of inventorship as to the other Biocon Patents because their claims are directed to other inventions than what Y-Trap identified as being conceived by Drs. Bedi and Ravi.

**1. Y-Trap Fails To State A Claim Of Inventorship As To A Protein Fusion Where The “Targeting Moiety” Is Not “Anti-EGFR”**

The fusion protein sequences discussed above, and alleged to have been conceived by Drs. Bedi and Ravi consists of an “anti-EGFR antibody.” *See e.g.*, Compl. ¶¶ 5-7 (identifying disclosure

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<sup>9</sup> Ex. 23 (IPR Pet.) at 1-2 (filing notice that JHU was the real party-in-interest, and certifying “that the ’247 patent is available for inter partes review and that Petitioner [JHU] is not barred or estopped from requesting an inter partes review challenging the patent claims”).

of fusion proteins consisting of “anti-EGFR antibody”). The inventions claimed in U.S. Patent Nos. 9,340,617 (the ’617 patent) and 9,758,582 (the ’582 patent) are not fusion proteins consisting of an “anti-EGFR antibody.” Rather, these inventions claim targeting moieties that are “anti-HER2/neu” (the ’617 patent) and “anti-CTLA4” (the ’582 patent).<sup>10</sup> No where in the Complaint are “Anti-HER2/neu” or “anti-CTLA4” mentioned.

Further, as discussed above, the heavy and light chains alleged to have been conceived of and disclosed by Drs. Bedi and Ravi were alleged to be similar to Biocon’s Seq. ID Nos. 5 and 6 (the heavy and light chains in the ’247 patent). But the ’617 and ’582 patents claim different Biocon Seq. ID Nos. 1-2 and 7-8 for the light and heavy chains.<sup>11</sup> Finally, there is no allegation the named inventors did not invent these sequences with anti-HER2/neu or anti-CTLA4. Thus, the Complaint fails to state a plausible claim for correction of inventorship as to the ’617 patent or the ’582 patent, and the claim must be dismissed as to these patents. *See CODA*, 916 F.3d at 1358-59.

## **2. Y-Trap Fails To State A Claim Of Inventorship Of The Method Patents**

Y-Trap’s claim for correction of inventorship as to the Biocon patents that include method claims should be dismissed because none of the allegations in the Complaint state sufficient facts relating to the conception of any methods. There are six such Biocon method patents:

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|---|------------|--|
| 1 | 9,809,651  | 6 claims, all claiming methods of treating cancer cells. <i>See</i> Ex. 4.   |
| 2 | 10,144,934 | 14 claims, all claiming methods of preparing a therapeutically active antibody-peptide fusion protein. <i>See</i> Ex.5.    |
| 3 | 10,385,348 | 8 claims, all claiming methods of reducing tumor transforming growth factor-beta (TGF- $\beta$ ) levels. <i>See</i> Ex. 6. |

<sup>10</sup> *See* Ex. 2 (’617 patent), cl. 1 (claiming “A chimeric fusion protein . . . wherein the targeting moiety is Anti-HER2/neu”); Ex. 3, ’582 patent, cl. 1 (“ A chimeric fusion protein . . . wherein the targeting moiety is anti-CTLA4”).

<sup>11</sup> *See* Ex. 2 (’617 patent), cl. 1 (claiming “wherein the targeting moiety is Anti-HER2/neu having heavy chain SEQ ID NO: 1 and light chain SEQ ID NO: 2”); Ex. 3 (’582 patent), cl. 1 (claiming “wherein the targeting moiety is anti-CTLA4 having heavy chain SEQ ID NO: 7 and light chain SEQ ID NO: 8”).

|   |            |  |
|---|------------|--|
| 4 | 11,028,399 | 2 claims, all claiming methods for binding of a bispecific chimeric fusion protein to CTLA4 and PD-L1. <i>See</i> Ex. 7.     |
| 5 | 11,060,097 | 4 claims, all claiming methods of immunotherapy. <i>See</i> Ex. 8.   |
| 6 | 12,049,632 | 3 claims, 2 of which claim methods for binding of a bispecific chimeric fusion protein to EGFR1 and PD-L1. <i>See</i> Ex. 9. |

### III. Y-TRAP'S § 256 CLAIMS ARE BARRED BY LACHES

A presumption of laches arises from a delay of six or more years after the purported omitted inventor knew or should have known that the patent issued without naming him. *Serdarevic v. Advanced Med. Optics, Inc.*, 532 F.3d 1352, 1358 (Fed. Cir. 2008). When the presumption applies, the defendant will prevail by standing on the presumption alone unless the plaintiff successfully rebuts it. *Id.* at 1359 (“Once the presumption of laches has attached, the defendants could have remained utterly mute on the issue of prejudice and nonetheless prevailed.”) (emphasis in original). To rebut the presumption, the plaintiff must have sufficient evidence to show its delay was reasonable or excusable, or that the defendant did not suffer material prejudice. *Id.* at 1359-60.

Y-Trap will likely argue that time bars such as laches and statute of limitations cannot be adjudicated at the pleading stage, which is correct in some cases but not an immutable standard. Rather, dismissal based on the defense of laches is appropriate where the delay is evident on the face of the Complaint and facts evidencing unreasonableness of the delay, lack of excuse, and material prejudice to the defendant are set forth in the Complaint and other facts the court may consider on a 12(b)(6) motion. *See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 988 F.2d 1157, 1161 (Fed. Cir. 1993) (explaining “Rule 12(b)(6) motion may be grounded on an affirmative defense” and “defense of laches usually requires factual development beyond the content of the complaint” as “facts evidencing unreasonableness of the delay, lack of excuse, and material prejudice to the defendant, are seldom set forth in the complaint, and at this stage of the proceedings can not be decided against the complainant based solely on presumptions.”); *see also Blackstone Realty LLC v. F.D.I.C.*, 244 F.3d 193, 197 (1st Cir. 2001) (dismissal allowable where

facts establishing affirmative defense are clear on face of pleadings and review of complaint and documents appropriately considered under 12(b)(6) leave no doubt plaintiff's action is barred).

Here, Y-Trap has included in its Complaint enough detail to plead itself out of court. Its allegations demonstrate the existence of both (1) unreasonable and inexcusable delay, and (2) material prejudice to Biocon attributable to the delay.

Specifically, Y-Trap delayed over 6 years in bringing its claim for correction of inventorship on U.S. Patent Nos. 8,815,247; 9,340,617; 9,758,582; and 9,809,651. The facts pled together with information appropriately considered by the Court on a 12(b)(6) motion, leave no doubt that Y-Trap's long delay was unreasonable, inexcusable, and prejudicial to Biocon. Indeed, Y-Trap purposefully waited for Biocon and Bicara to undertake all of the work and significant financial burden to make the Biocon patented inventions a success—including waiting until after such success became apparent, until after Biocon and Bicara invested millions of dollars, until after defendants moved forward with the immense work of bringing BCA101 into clinical trials, until after defendants began seeing clinically meaningful results, and waiting until Bicara's IPO to suddenly raise inventorship despite being on notice of this issue even before the first patent issued in 2014. *See, e.g.*, Compl. ¶¶ 11, 21, 65-67, 80-88. Count 1 should be dismissed as barred by the equitable defense of laches.

**A. The Complaint And Facts Of Public Record Demonstrate That Y-Trap Knew Or Should Have Known About The Biocon Patents Starting In 2014**

The law is “well-settled” that in the context of laches “the plaintiff is chargeable with such knowledge as he might have obtained upon inquiry, provided the facts already known by him were such as to put upon a man of ordinary intelligence the duty of inquiry.” *Advanced Cardiovascular*, 988 F.2d at 1162. This well-settled law applies to § 256 actions to correct inventorship. *Id.*



### **1. Y-Trap Cannot Disclaim Knowledge Of The Biocon Patents**

Y-Trap is chargeable with the information known to its executives and co-founders Drs. Bedi and Ravi. The Complaint pleads facts that, along with facts of public record, demonstrate that Drs. Bedi and Ravi knew or should have known of the issuance of the '247 patent in 2014, and they (and thus Y-Trap) had sufficient knowledge to put them under a duty to inquire about any Biocon patents relating to the same subject matter as the '789 Bedi IP, starting with issuance of the '247 patent and following with patents in the same family.

### **2. Y-Trap Knew Or Should Have Known About The Biocon Patents, Because It Had Actual Notice Of Biocon's '247 Patent During Examination Of The Bedi '524 Patent And Had A Duty To Inquire Based On Events Starting In 2012 Through 2014**

The '247 patent was made of record and cited by the patent examiner in November 2014 during examination of the Bedi '524 patent (the first of the patents to issue related to the '789 Bedi IP), specifically in the Notice of Allowability, attached to the Notice of Allowance, and mailed to JHU on November 24, 2014. Ex. 19. Y-Trap cannot get away from this knowledge. Thus, based on the circumstances pled and the facts of public record, Y-Trap—through its founders and executives Drs. Bedi and Ravi, and by JHU's knowledge attributable to its alleged exclusive licensee—knew or should have known about the issuance of the '247 patent in 2014.

Further, according to the Complaint and facts of public record, from sometime in and around 2012 through 2014, IATRICa (and therefore Drs. Bedi and Ravi), JHU, and Biocon were involved in a dispute relating to ownership of the '789 Bedi IP, *i.e.*, whether it belonged to JHU or IATRICa. Compl. ¶¶ 27, 45-47. Y-Trap's reliance on the idea that Biocon dropped a dispute as to ownership of the '789 Bedi IP is no excuse for Y-Trap's unreasonable delay in filing inventorship claims on the Biocon Patents. Indeed, not only are the two issues distinct, the public

records also show that the dispute was ongoing in 2014.<sup>12</sup> Biocon filed an amended books and records complaint in March 2014, and the parties only settled the issue of IATRICa being required to turn over books and records as of March 21, 2014, but the underlying ownership dispute—the reason for the books and records demand—remained unsettled.<sup>13</sup>

### **3. Y-Trap Also Knew About The Later Issuing Biocon Patents In The Same Family Or Should Have Known Because It Had An Ongoing Duty To Inquire About Related Patents Based On Post-2014 Events**

The facts alleged in the Complaint and of public record further demonstrate that Y-Trap knew or should have known about the later issuing Biocon patents in the same family. It had an ongoing duty of inquiry once it was aware of the first patent to issue in the family, particularly in light of additional post-2014 events including JHU’s IPR Petition in 2015, the PTAB’s Denial in 2016, and issuance of each of Y-Trap’s licensed patents—which Y-Trap’s founders are named inventors of and that all cite the ’247 patent on their face. Exs. 23 24, 27.

Y-Trap’s continued duty to inquire about additional Biocon patents is demonstrated by the circumstances that JHU petitioned the PTAB to institute an IPR against Biocon in 2015, during the same timeframe Y-Trap is alleged to have been founded to develop products from the same IP

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<sup>12</sup> Prior state court filings, of public record, show that Drs. Bedi and Ravi knew about the dispute throughout the period from 2012 through 2014. According to Y-Trap’s own arguments and pleadings, this ought to have put them under a duty of inquiry (chargeable to Y-Trap) as to what other patents Biocon may have been pursuing or prosecuting in 2012. Biocon formally served IATRICa with a certified demand letter (which was addressed care/of Dr. Bedi as CEO and President of IATRICa) to inspect IATRICa’s books and records in June 2012. Ex. 21. Additionally, the letter and a Verified Complaint accused Dr. Bedi of engaging in self-dealing and waste of corporate assets by filing and then assigning IATRICa’s rights in pending provisional applications—the JHU 2010 Provisional Application and JHU 2011 Provisional Application—to JHU. *See* Ex. 20 (2013 Verified Compl.) at ¶¶ 1-3, 20, 27, 30, 32, 38 and Ex. 21 (Exhibit C - June 2012 Books & Records Demand Letter to the 2013 Verified Compl.) at 2-3.

<sup>13</sup> *See* Ex. 25 (2014 Amended Compl.) at ¶ 15 (“[T]he parties negotiated and entered into a settlement agreement. Pursuant to the parties’ settlement agreement, IATRICa agreed to produce certain books and records and Biocon agreed to file an amended complaint while reserving all of its legal rights”); Ex 26 (Stipulation of Dismissal).

being asserted in the IPR. Specifically, the Bedi '524 patent issued on March 31, 2015, after citing the '247 patent as being “of record” in the public prosecution history in 2014. Ex. 19 at 8 (internal page 4 following Notice of Allowability attached to Notice of Allowance). Drs. Bedi and Ravi “cofounded Y-Trap to develop products from the '789 Bedi IP” in September 2015, and sometime in 2016 allegedly “procured an exclusive license from JHU to this intellectual property.” Compl. ¶ 48. Contemporaneous with this timeline, JHU filed a request for an IPR challenging the '247 patent on the basis of the Bedi '524 patent on November 10, 2015, which IPR request was not denied until 2016. Ex. 23 (IPR Pet.); Ex. 24 (IPR Decision). And JHU’s IPR specifically raised the issue of whether or not the Biocon patent family, as represented by the Biocon '724 patent, was functionally a copy of (*i.e.*, was anticipated or made obvious by) the '789 Bedi IP, as represented by the Bedi '524 patent.

In short, Y-Trap already knew about the Biocon patents and any inventorship claim by 2014, and to the extent it alleges it did not, even granting all reasonable inferences to Y-Trap, the facts are such that it is simply not reasonable for an individual of ordinary intelligence, under the circumstances here, to fail to inquire about and learn of the Biocon patents, especially the issuance of the '247 patent by 2014. And following issuance of that patent in 2014, Y-Trap was likewise on notice and a continued duty to inquire as (1) Biocon had been continuously and publicly prosecuting its patents in this same family, with patents issuing again in 2016, 2017, 2018, and 2019 and then again in 2021 and 2024 and (2) JHU’s patents issuing in 2015, 2016, 2017, 2019 and 2022 (related to the '789 Bedi IP) (Ex. 27) all cite the '247 patent as a reference on the very first page except for the last patent which cites it on the second page. *See Wanlass v. Gen. Elec. Co.*, 148 F.3d 1334, 1338-39 (Fed. Cir. 1998) (“The Supreme Court has consistently imputed to parties who failed to examine readily available information the knowledge contained in it and the

results of inquiries that the knowledge would have motivated a reasonable man to conduct.”); *see also Expert Microsystems, Inc. v. Univ. of Chicago*, 712 F. Supp. 2d 1116, 1121 (E.D. Cal. 2010) (“Y-Trap was sufficiently put on notice of his potential inventorship claims by reading the first page of the patents.”).

**B. Y-Trap’s Delay In Filing Suit After It Knew Or Should Have Known About The Biocon Patents Since 2014 Is Unreasonable And Inexcusable.**

The pleadings establish that Y-Trap delayed ten-years (from 2014 to 2024) since it knew or should have known about its inventorship claim and the ’247 patent and more than six-years since it knew or should have known about U.S. Patent Nos. 9,340,617; 9,758,582; and 9,809,651. This is although, JHU alleged the ’247 patent was invalid as anticipated and obvious by filing an IPR on those grounds based on the ’789 Bedi IP. Y-Trap never even alleges it did not know about the issuance of the ’247 patent or any other of the Biocon Patents, only that it allegedly did not know about plans to develop and commercialize BCA101 until 2021. *See, e.g.,* Compl. ¶7.

The excuses that Y-Trap does allege are irrelevant to its inventorship claims. Its alleged lack of knowledge about the development of BCA101 has nothing to do with the purportedly incorrect identification of inventors on patents. It may explain why Y-Trap did not see the proverbial pot of gold at the end of the rainbow, but holding back an inventorship claim while the allegedly incorrect inventors invest time, money, and effort into developing a potential commercial product is the opposite of reasonable. To the contrary, it is proof of unreasonable delay and of harm to Biocon (and Bicara) from that delay. Nor does IATRICa’s purported belief that its dispute with Biocon over ownership of a patent naming Bedi as the inventor which he assigned to JHU (instead of assigning to IATRICa) had fizzled out when Biocon and IATRICa resolved the Delaware books and records have anything to do with inventorship of Biocon patents that were not (and could not) have been at issue in a books and records case.

### C. Biocon Will Suffer Material Prejudice Attributable To The Delay

Economic prejudice from delay arises when the defendant (and possibly others) will suffer the loss of investments or incur damages that likely would have been prevented by earlier suit. *Serdarevic*, 532 F.3d at 1360. The Complaint pleads facts demonstrating this very economic prejudice to Biocon. Y-Trap alleges that Biocon invested heavily in the patents, spending years in patent prosecution, and that Biocon and Bicara entered into license agreements to use the patents, and engaged in years of work and expended tens-of-millions of dollars for that work in development of the patents. *See, e.g.*, Compl. ¶¶ 6 & n.2, 21, 24, 40, 52. This is material economic prejudice to Biocon. *See, e.g., Expert Microsystems*, 712 F. Supp. 2d at 1123 (finding economic investment in patents made by entering into license agreements to use the patents supported finding economic prejudice); *Moore v. Broadcom Corp.*, No. C06–05647 MJJ, 2008 WL 425932, at \*7 n.4 (N.D. Cal. Feb. 14, 2008) (finding defendant’s licensing of patent supported finding economic prejudice). Y-Trap’s delay was also calculated to prejudice Biocon. Y-Trap knew well in advance of the inventorship claim alleged here but intentionally delayed to see how commercial development (after Biocon invested its resources) played out before bringing suit. Worse, given interactions with IATRICa and the failed IPR, Biocon had every reason to believe JHU and Drs. Bedi and Ravi (and therefore Y-Trap) would not make an inventorship claim. To allow Y-Trap to do so now would be inequitable, and Count 1 should be dismissed.

### IV. THERE IS NO PERSONAL JURISDICTION OVER BIOCON WITH RESPECT TO Y-TRAP’S STATE-LAW CLAIMS

Y-Trap contends this Court has personal jurisdiction over Biocon under Federal Rule of Civil Procedure 4(k)(2). Compl. ¶ 22. However, because that rule applies only to federal claims, and the statute giving rise to Y-Trap’s federal claim—35 U.S.C. § 256—does not provide for nationwide service of process, the Court “must conduct the same personal jurisdiction inquiry as

in a diversity case, focusing on the defendant’s contacts with Massachusetts rather than with the United States as a whole.” *Motus, LLC v. CarData Consultants Inc.*, 520 F. Supp. 3d 87, 91 (D. Mass. 2021), *aff’d*, 23 F.4th 115 (1st Cir. 2022). The answer to the jurisdictional question as correctly posed, *i.e.*, whether Biocon is subject to specific jurisdiction in Massachusetts without reference to Rule 4(k)(2), is “no.” Accordingly, even if Y-Trap’s federal claim (Count I) survives Biocon’s motion to dismiss, Y-Trap’s state-law claims (Counts II, V, and VI) must be dismissed for lack of personal jurisdiction. *See Debreceeni v. Bru-Jell Leasing Corp.*, 710 F. Supp. 15, 19 (D. Mass. 1989) (“Where a complaint contains two claims, only one of which arises under federal law, there must be an independent basis for the assertion of personal jurisdiction for each claim. Jurisdiction over one claim does not imply jurisdiction over another.”).<sup>14</sup>

A plaintiff “must demonstrate that defendants have made sufficient contacts with the forum state to justify the exercise of either specific or general jurisdiction by this Court.” *Mueller Sys., LLC v. Robert Teti & Itet Corp.*, 199 F. Supp. 3d 270, 277-78 (D. Mass. 2016). Y-Trap does not allege that Biocon is subject to general jurisdiction in Massachusetts, nor could it. General jurisdiction requires the defendant to be “essentially at home” in the state. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). For corporations, home is the place of incorporation and the principal place of business. *BNSF Ry. Co. v. Tyrrell*, 581 U.S. 402, 413 (2017). Biocon is “at home” in India, where it is incorporated and has its principal place of business. Compl. ¶ 17; Jamil Decl. ¶ 2.

Nor is Biocon subject to specific jurisdiction in Massachusetts on Y-Trap’s state-law claims. The three-pronged test for specific jurisdiction focuses on “(1) whether the claim directly

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<sup>14</sup> If Y-Trap argues for “pendent personal jurisdiction” over its state-law claims, the Court should reject it. The First Circuit “has never had occasion to address whether pendent personal jurisdiction exists at all[.]” *Mojtabai v. Mojtabai*, 4 F.4th 77, 88 (1st Cir. 2021).

arises out of, or relates to, the defendant’s forum state activities; (2) whether the defendant’s in-state contacts represent a purposeful availment of the privilege of conducting activities in the forum state . . . ; and (3) whether the exercise of jurisdiction is reasonable.” *A Corp. v. All Am. Plumbing, Inc.*, 812 F.3d 54, 59 (1st Cir. 2016). All three requirements must be satisfied. *Rosenthal v. Bloomingdales.com, LLC*, 101 F.4th 90, 95 (1st Cir. 2024).

*First*, none of Biocon’s alleged wrongful conduct occurred in Massachusetts. The complained-of assertions of inventorship—to the extent they could give rise to a state-law claim—occurred before the USPTO in Virginia and the Controller General of Patents in India. Compl. ¶¶ 40-44, 55-63. The complained-of “copying” occurred in India. *Id.* ¶¶ 41, 42. The Transfer and License Agreement between Biocon and Bicara, *see id.* ¶ 73, was executed by Biocon in India, is governed by English law, and provides for arbitration in England. Jamil Decl. ¶¶ 3-5. And if the location of the purported harm matters, which it does not, Y-Trap is a Delaware corporation located in California. Compl. ¶ 15. It has no connection to Massachusetts. “[T]he phrase ‘relate to’ incorporates real limits,” and requires a “strong ‘relationship among the defendant, the forum, and the litigation’—the ‘essential foundation’ of specific jurisdiction.” *Ford Motor Co. v. Montana Eighth Jud. Dist. Ct.*, 592 U.S. 351, 362, 365 (2021). That foundation is lacking here.

*Second*, even if Y-Trap satisfied the relatedness prong, specific jurisdiction would still be lacking under the “purposeful availment” prong. Y-Trap’s conclusory allegation that Biocon purposefully availed itself of the benefits and protections of Massachusetts law by entering into agreements with Bicara, *see* Compl. ¶¶ 21, 23, ignores the fact that Bicara is not the one seeking to hale Biocon into a Massachusetts court. Biocon could not have foreseen being haled into court in Massachusetts for Y-Trap’s claims. *See A Corp.*, 812 F.3d at 60 (noting the focus of the inquiry is on the “defendant’s intentionality, and the cornerstones of purposeful availment—voluntariness

and foreseeability”). Indeed, Biocon could not have foreseen being haled into court in Massachusetts even by Bicara, given that their contract is governed by English law with dispute resolution in London. Jamil Decl. ¶ 5; *see also Vapotherm, Inc. v. Santiago*, 38 F.4th 252, 262 (1st Cir. 2022) (finding choice-of-law clause for Maryland indicated lack of notice that defendant would be haled into New Hampshire court).<sup>15</sup>

Finally, Biocon’s complained-of statements to the USPTO and Indian Patent Office do not remotely demonstrate purposeful availment of the benefits of Massachusetts law, nor do that have any connection to Massachusetts.<sup>16</sup> Accordingly, Y-Trap’s state-law claims against Biocon must be dismissed for lack of personal jurisdiction.

## V. Y-TRAP’S STATE-LAW CLAIMS ARE TIME BARRED

Y-Trap’s state-law claims also should be dismissed based on the statutes of limitations. “Granting a motion to dismiss based on a limitations defense is entirely appropriate when the pleader’s allegations leave no doubt that an asserted claim is time-barred.” *LaChapelle v. Berkshire Life Ins. Co.*, 142 F.3d 507, 509 (1st Cir. 1998). Such is the case here.

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<sup>15</sup> Nor does Y-Trap’s passing reference to the purported presence in Massachusetts of Biocon Biologics, Inc., which has nothing to do with this lawsuit, provide grounds for specific jurisdiction. *See* Compl. ¶ 21. Biocon Biologics, Inc., is a Delaware corporation with its principal place of business in New Jersey. Biocon Biologics, Inc., has no agreement to manufacture any products for Bicara, and has not manufactured any products for Bicara, including without limitation the “bifunctional antibodies,” alleged in paragraph 21 of Y-Trap’s Complaint. Jamil Decl. ¶ 8; *see also Andresen v. Diorio*, 349 F.3d 8, 12 (1st Cir. 2003) (even if parent corporation that has “overall financial and policy control,” that is not enough because such control “is inherent in ownership and, if overall control were sufficient, every parent would be present wherever a wholly owned subsidiary was present in a state.”).

<sup>16</sup> Given that specific jurisdiction is lacking under each of the relatedness and purposeful availment prongs independently, the Court need not reach the reasonableness analysis. *Vapotherm*, 38 F.4th at 263. Nonetheless, the assertion of personal jurisdiction would not be reasonable given the lack of Massachusetts’ interest in adjudicating claims by a California company against an Indian company for alleged wrongful actions in India and Virginia. *See Sawtelle v. Farrell*, 70 F.3d 1381, 1394 (1st Cir. 1995)).



To the extent that patenting activities can give rise to state-law claims, the complained-of actions by Biocon—the alleged “copying” of the Bedi ’789 IP and naming only Biocon inventors on the Biocon Patents—occurred long before the expiration of the applicable limitations periods, which are October 22, 2021 for Y-Trap’s unjust enrichment and civil conspiracy claims, and October 22, 2022 for its Chapter 93A claim.<sup>17</sup> Indeed, nine of Biocon’s patent applications published—and six U.S. patents issued—before October 2020. *See* Exs. 1-6. Biocon’s activities were “notice to the world” of its assertion of rights as the sole owner of the Biocon Patents, and Y-Trap is charged with knowing that. *See Wise v. Hubbard*, 769 F.2d 1, 2 (1st Cir. 1985).

Y-Trap also had actual knowledge. For example, Biocon’s ’247 patent is cited on the face of JHU patents through which Y-Trap has knowledge. *See* Ex. 27 (the Bedi ’524 patent, issued March 31, 2015). And in 2015, JHU sought to invalidate Biocon’s ’247 patent in proceedings before the USPTO, in which it was publicly stated that the patent was owned by Biocon.<sup>18</sup> Ex. 23 (IPR Pet.) at cover page. Thus, Y-Trap was specifically on notice that the Biocon Patents were being prosecuted and developed well before October 2020. *See Stark v. Advanced Magnetics, Inc.*, 736 N.E.2d 434, 442 (Mass. App. Ct. 2000) (finding c. 93A claim was time barred where issuance of patent and annual report “were sufficient to alert the plaintiff that AMI was in breach of its alleged agreement with him and that he had been harmed”). Accordingly, Y-Trap’s state-law claims must be dismissed as untimely.<sup>19</sup>

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<sup>17</sup> M.G.L. ch. 260, §§ 2A, 5A; *Kaiser v. Kirchick*, 662 F. Supp. 3d 76, 94 (D. Mass. 2023); *Epstein v. C.R. Bard, Inc.*, 2004 WL 1598912, at \*3 (D. Mass. July 19, 2004); *Latson v. Plaza Home Mortg., Inc.*, 708 F.3d 324, 326 (1st Cir. 2013).

<sup>18</sup> Because Y-Trap’s claims seemingly flow through JHU, it is bound by JHU’s statements.

<sup>19</sup> Biocon joins in Bicara’s statute of limitations arguments (Dkt. No. 45, at 9-13) as well.

## **VI. Y-TRAP FAILS TO STATE A CLAIM UNDER M.G.L. ch. 93A**

The Court should dismiss Y-Trap’s claim under M.G.L. ch. 93A (Count II) for three additional and independent reasons. First, there was no commercial transaction between Y-Trap and Biocon. Second, the allegedly unfair or deceptive acts or practices did not occur primarily and substantially within Massachusetts. Third, Y-Trap has failed to allege that Biocon’s allegedly unfair or deceptive conduct caused Y-Trap any loss of money or property.

### **A. There Was No Commercial Transaction Between Y-Trap And Biocon**

As a threshold matter, “[Chapter 93A, § 11] requires that there be a commercial transaction between a person engaged in trade or commerce [and] another person engaged in trade or commerce.” *Linkage Corp. v. Trustees of Boston Univ.*, 679 N.E.2d 191, 206-07 (Mass. 1997). Because Y-Trap does not allege it had a commercial transaction with Biocon, its Chapter 93A claim must be dismissed. *See, e.g., JT IP Holding, LLC v. Florence*, No. 1:20-CV-10433-IT, 2024 WL 4190044, at \*11 (D. Mass. Sept. 12, 2024) (granting summary judgment for defendant dismissing c. 93A claim where plaintiff failed to present any evidence of commercial transaction with the defendants).

### **B. Biocon’s Actions Did Not Occur Primarily And Substantially In Massachusetts**

To state a Chapter 93A claim, “the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice” must have “occurred primarily and substantially within the commonwealth.” *See* Mass. Gen. Laws ch. 93A, § 11, eighth par. Massachusetts courts ask if “the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth.” *Kuwaiti Danish Comput. Co. v. Dig. Equip. Corp.*, 781 N.E.2d 787, 799 (Mass. 2003).

Y-Trap alleges that Biocon engaged in unfair competition by “repeatedly and baselessly claiming inventorship and ownership of the ’789 Bedi IP and the inventions disclosed and claimed therein.” Compl. ¶ 111. Those circumstances were not centered in Massachusetts. *See, e.g.*, Compl. ¶¶ 40-44, 55-63 (alleging claims made to the USPTO and Indian Patent Office). Y-Trap attempts to tether its claim to Massachusetts by alleging that (i) Biocon’s acts were “received and acted upon in Massachusetts” by other entities (Bicara and Biocon Biologics, Inc.), and (ii) Y-Trap was harmed in Massachusetts because it “planned” to engage in research on its own hypothetical product with some unnamed Massachusetts-based counterparty. *Id.* ¶¶ 114, 117. But neither the actions of others in Massachusetts nor the harm allegedly felt by Y-Trap establish a “center of gravity” in the Commonwealth. *See, e.g., Warren Envtl., Inc. v. Source One Envtl., Ltd.*, No. CV 18-11513-RGS, 2020 WL 1974256, at \*10-11 (D. Mass. Apr. 24, 2020) (dismissing c. 93A claim where the bulk of the alleged transgressions occurred primarily and substantially outside of Massachusetts). What matters are the “the actions and transactions” of the *defendant* “constituting the alleged unfair method of competition or the unfair or deceptive act or practice.” Mass. Gen. Laws ch. 93A, § 11, eighth par. *See also First Sec. Bank, N.A. v. Northwest Airlines, Inc.*, No. CIV. A. 95-12103-RGS, 2001 WL 92175, at \*5 (D. Mass. Jan. 3 2001) (“The plaintiffs, it is true, felt the impact of the loss in Massachusetts, but . . . that fact is not determinative.”). As Biocon’s alleged conduct did not occur primarily and substantially in Massachusetts, Y-Trap’s Chapter 93A claim should be dismissed.

### **C. Y-Trap Does Not Allege Cognizable Loss Of Money Or Property**

Y-Trap’s Chapter 93A claim also fails because it has not alleged that it suffered a loss of money or property as a result of Biocon’s allegedly unfair and deceptive methods of competition. “A Section 11 plaintiff must show that the defendant’s alleged unfair or deceptive method, act, or practice caused a loss of money or property.” *LimoLiner, Inc. v. Dattco, Inc.*, 919 F.3d 86, 90 (1st

Cir. 2019). “A plaintiff’s failure to establish both factual causation and proximate causation is fatal to her Chapter 93A claim.” *Id.*

The type of harm Y-Trap alleges—“loss and diminution of its competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace,” Compl. ¶ 116—do not qualify as monetary or property losses. “Money means money, not time, and property means the kind of property that is purchased or leased, not such intangibles as a right to a sense of security, to peace of mind, or to personal liberty.” *Arthur D. Little, Inc. v. Dooyang Corp.*, 147 F.3d 47, 56 (1st Cir. 1998); *see also Ratchford v. Orange Lantern, Inc.*, 720 F. Supp. 3d 64, 78 (D. Mass. 2024) (dismissing 93A claim where defendant’s allegedly false and misleading advertising campaign did not cause plaintiffs to suffer a loss of money or property). Y-Trap makes a veiled attempt at pleading a loss of money by speculating that it also suffered “lost licensing revenue.” Compl. ¶ 118. But this allegation is speculative and conclusory and not a foreseeable consequence of Biocon’s allegedly false claims of inventorship, which form the basis for Y-Trap’s Chapter 93A claim against Biocon. *See Iannacchino v. Ford Motor Co.*, 888 N.E.2d 879, 886 n.12 (Mass. 2008) (requiring “causal connection between the deception and the loss and that the loss was foreseeable as a result of the deception”) (quoting *International Fid. Ins. Co. v. Wilson*, 443 N.E.2d 1308, 1314 (Mass. 1983)). Accordingly, Y-Trap’s Chapter 93A claim should be dismissed for this reason as well.

## **VII. Y-TRAP FAILS TO STATE A CLAIM FOR UNJUST ENRICHMENT**

The Court should dismiss Y-Trap’s claim for unjust enrichment (Count V) for several independent reasons.<sup>20</sup> First, an unjust enrichment claim is not cognizable where, as here, a plaintiff has an adequate remedy at law, regardless of whether such a claim is viable. *Shaulis v.*

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<sup>20</sup> Bicara accurately sets forth the elements of unjust enrichment. Dkt. No. 45, at 20-21.

*Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017) (holding that plaintiff’s unjust enrichment claim failed because “a party with an adequate remedy at law cannot claim unjust enrichment”). Y-Trap’s Complaint includes claims for violation of M.G.L. ch. 93A and correction of inventorship under 35 U.S.C. § 256. The disposition of those claims is irrelevant; their mere availability is a bar to a claim of unjust enrichment. *See Tomasella v. Nestlé United States*, 962 F.3d 60, 84 (1st Cir. 2020) (dismissing unjust enrichment and c. 93A claims, and noting that deficiency in c. 93A claim “is beside the point”); *Mack v. Cultural Care Inc.*, No. 1:19-CV-11530-ADB, 2020 WL 4673522, at \*9 (D. Mass. Aug. 12, 2020) (same); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 332 F. Supp. 3d 446, 474 (D. Mass. 2018) (dismissing unjust enrichment claim where plaintiff also pled a patent-based claim, even though patent-based claim was not viable).

Second, Y-Trap fails to plead sufficient facts to support a claim for unjust enrichment. Most notably, Y-Trap fails to allege that it conferred a benefit on Biocon. Instead, Y-Trap alleges that “Biocon’s actions conferred a benefit on Biocon by allowing it to earn significant return on its investment in Bicara,” and Biocon “conferred a benefit on Bicara.” Compl. ¶¶ 132, 139. Accordingly, Y-Trap’s claim fails as a matter of law because it “does not establish a monetary or property benefit that [Y-Trap] conferred on [Biocon].” *Columbia Plaza Assocs. v. Ne. Univ.*, 227 N.E.3d 999, 1018 (Mass. 2024).

Finally, whether retention of a benefit is unjust “turns on the reasonable expectations of the parties.” *Metro. Life Ins. Co. v. Cotter*, 984 N.E.2d 835, 850 (Mass. 2013) (citation omitted). Y-Trap has no reasonable expectation of receiving any benefit from the relationship between Biocon and Bicara.<sup>21</sup> Therefore, Y-Trap’s unjust enrichment claim should be dismissed.

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<sup>21</sup> Nor is there anything unjust about “Biocon, as a major investor in Bicara stand[ing] to earn [a] significant return on its initial investment,” as Y-Trap alleges. Compl. ¶ 139.

### VIII. Y-TRAP FAILS TO STATE A CLAIM FOR CIVIL CONSPIRACY

This Court should dismiss Count VI of the Complaint because Y-Trap fails to plead facts that establish a plausible claim of a civil conspiracy. The concerted action theory on which Y-Trap relies “applies to a common plan to commit a tortious act where the participants know of the plan and its purpose and take affirmative steps to encourage the achievement of the result.” *Greene v. Philip Morris USA Inc.*, 208 N.E.3d 676, 683 (Mass. 2023). Y-Trap alleges generally that Biocon and Bicara acted “in concert” and “conspired to weaken the ’789 Bedi IP and copied the inventions disclosed in the ’789 Bedi IP to enable themselves to develop and commercialize technologies competing directly with Y-Trap, and improve their competitive position, and increase their market share in the field.” Compl. ¶¶ 145-146. But there are no details as to what role Biocon and Bicara had in the alleged conspiracy, or any allegations of a common plan to “unlawfully disrupt Y-Trap’s ability to compete in the market.” Compl. ¶ 144.<sup>22</sup> Furthermore, none of these allegations identify an underlying tortious act in furtherance of an agreement between Biocon and Bicara. *See, e.g., Massachusetts ex rel. Powell v. Holmes*, 546 F. Supp. 3d 58, 81 (D. Mass. 2021) (dismissing civil conspiracy claim where “the complaint fails to allege the existence of an underlying tort”).

Finally, to the extent Y-Trap bases its conspiracy claim on allegedly fraudulent actions, *see* Compl. ¶¶ 8, 51, it has failed to “state with particularity the circumstances constituting fraud,” as required by Fed. R. Civ. P. 9(b). “[M]ere allegations of . . . corruption or conspiracy, averments to conditions of mind, or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such accusations are repeated.” *Hayduk v.*

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<sup>22</sup> *See, e.g., Atkinson v. Town of Rockport*, No. 11-11073-NMG, 2012 WL 4888423, at \*4 (D. Mass. July 30, 2012) (“[D]espite repeated claims that . . . defendants conspired with each other, there are no details as to ‘what part each defendant had in the alleged conspiracy,’ or any ‘allegations of a common understanding between the conspiring parties.’ . . . The generalized conclusion that a conspiracy existed is insufficient to state a cognizable claim.”).

*Lanna*, 775 F.2d 441, 444 (1st Cir. 1985). “Without supporting facts regarding the circumstances surrounding the formation of the conspiracy to defraud plaintiffs or plaintiffs’ basis for believing that a conspiracy existed for the purpose of defrauding them, the allegation becomes a conclusional accusation of the sort that is proscribed by Rule 9(b).” *Id.* For all of these reasons, Y-Trap’s civil conspiracy claim should be dismissed.<sup>23</sup>

### VIII. FEDERAL PATENT LAW PREEMPTS Y-TRAP’S STATE-LAW “COPYING” CLAIMS

State-law claims for “copying” unpatented subject matter are preempted by federal law absent added elements such as breach of contract or misappropriation of trade secret. This is because the federal patent laws do not just determine what is protected, they also determine what is not protected. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (“To a limited extent, the federal laws must determine not only what is protected, but also what is free for all to use.”); *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232-33 (1964) (“[B]ecause of the federal patent laws a State may not, when the article is unpatented and uncopyrighted, prohibit the copying of the article itself or award damages for such copying.”).

For example, the plaintiff in *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369 (Fed. Cir. 2005), employed two engineers who were asked by Ford to help design a part for air conditioners. They came up with a design and presented it to Ford, “[n]otwithstanding the absence of any written agreement or confidentiality undertaking.” *Id.* at 1372. After Ford commercialized a design that seemingly embodied their own solution, their company sued Ford for unjust enrichment and correction of inventorship of a patent that Ford had obtained. The district court granted summary judgment dismissing the unjust enrichment claim as preempted, and ruled

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<sup>23</sup> As Y-Trap alleges that Biocon and Bicara engaged in civil conspiracy together, Biocon refers to Bicara’s arguments on that issue. Dkt. No. 45, at 22-24.

against Ultra-Precision on the inventorship claim after a bench trial. On appeal, Ultra-Precision argued that unjust enrichment “permits a plaintiff to present evidence to a jury of a defendant’s unjust benefit from the use of technical information given to defendant by plaintiff, regardless of plaintiff’s property interest, *vel non*, in the technical information.” *Id.* at 1377. The Federal Circuit rejected this argument, finding no exception from federal preemption based on alleged copying of an unpatented idea, explaining that “[a]llowing states to enforce contracts is consistent with allowing states to protect against misappropriation of trade secrets,” whereas “unjust enrichment has the potential to take aim at the federal scheme.” *Id.* at 1382.

Here, Y-Trap does not and cannot allege (i) breach of a contract between it and Biocon, or (ii) misappropriation by Biocon of a trade secret owned by Y-Trap. First and most obviously, Y-Trap did not exist at the time of the alleged copying. *Compare* Compl. ¶ 48 (Y-Trap was founded in 2015) *with id.* ¶ 30 (disclosure to Biocon in 2010); ¶ 40 (Biocon filed patent application in 2012). Regardless of what was disclosed to whom and under what circumstances, no rights belonging to Y-Trap could have been impaired because Y-Trap did not exist. Y-Trap’s attempt to benefit from Biocon’s alleged use of technical information “regardless of plaintiff’s property interest, *vel non*, in the technical information” fares no better than Ultra-Precision’s analogous claim. 411 F.3d at 1377.

Second, the so-called Bedi ’789 IP entered the public domain by publication before Biocon is alleged to have copied it into the “Copycat Biocon IP.” Specifically, the moniker “Bedi ’789 IP” comes from the publication number of WO 2011/10987, Compl. ¶ 2, n.1, which published on September 9, 2011. Ex. 22 (WO 2011/109789) at 1. But the alleged Copycat Biocon IP started with an Indian patent application (1689/CHE/2012) filed on April 30, 2012, Compl. ¶ 40, which is more than six months after the Bedi ’789 IP entered the public domain.



Y-Trap’s allegation of copying is the foundation of all its state-law claims. But federal patent law preempts state-law claims based on copying publicly disclosed information. *See Bonito Boats*, 489 U.S. at 156 (“ideas once placed before the public without the protection of a valid patent are subject to appropriation without significant restraint”); *Ultra-Precision*, 411 F.3d at 1380 (no state-law claim for unpatented technology disclosed in plaintiff’s own patents). Y-Trap may someday have a potential remedy in the form of claims for patent infringement. But its state-law claims for “copying” alleged intellectual property (that it does not own, and which was publicly disclosed at least as early as September 2011) are preempted.

### **CONCLUSION**

For the foregoing reasons, Y-Trap’s Complaint should be dismissed.

Date: January 21, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Michael T. Maroney, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on this 21st day of January, 2025.

/s/ Michael T. Maroney

Michael T. Maroney

Dated: January 21, 2025